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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,156	08/22/2003	Dirk Stenkamp	I/1387	1272

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/647,156

Applicant(s)

STENKAMP ET AL.

Examiner

Tamthom N. Truong

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>attached</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group 1: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-1, and pharmaceutical composition thereof, classified in classes 514 and 546, various subclasses depending on substituents. Election of species will be required if this group is elected.
- Group 2: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-2, and pharmaceutical composition thereof, classified in classes 514 and 546, various subclasses depending on substituents. Election of species will be required if this group is elected.
- Group 3: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-3, and pharmaceutical composition thereof, classified in classes 514 and 546, various subclasses depending on substituents. Election of species will be required if this group is elected.
- Group 4: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-4, I-5, or I-6, and pharmaceutical composition thereof, classified in classes 514 and 546, various subclasses depending on substituents. Election of species will be required if this group is elected.

- Group 5: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-7, and pharmaceutical composition thereof, classified in classes 514 and 544, various subclasses depending on substituents. Election of species will be required if this group is elected.
- Group 6: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-8, and pharmaceutical composition thereof, classified in classes 514 and 544, various subclasses depending on substituents. Election of species will be required if this group is elected.
- Group 7: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-9, and pharmaceutical composition thereof, classified in classes 514 and 544, various subclasses depending on substituents. Election of species will be required if this group is elected.
- Group 8: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-10, and pharmaceutical composition thereof, classified in classes 514 and 544, various subclasses depending on substituents. Election of species will be required if this group is elected.
- Group 9: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-11, and pharmaceutical composition thereof, classified in classes 514 and 544, various subclasses depending on substituents. Election of species will be required if this group is elected.

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Group 10: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-12, and pharmaceutical composition thereof, classified in classes 514 and 546, various subclasses depending on substituents. Election of species will be required if this group is elected.

Group 11: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-13, and pharmaceutical composition thereof, classified in classes 514 and 546, various subclasses depending on substituents. Election of species will be required if this group is elected.

Group 12: Claims 1-3, 6, 9-11, 13, 16, 20-23, 26-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-14, and pharmaceutical composition thereof, classified in classes 514 and 546, various subclasses depending on substituents. Election of species will be required if this group is elected.

Group 13: Claims 1-3, 6, 9-11, 13, 16, 20-30, 32 and 44 (part of each), drawn to compounds wherein formula I is formula I-15, and pharmaceutical composition thereof, classified in classes 514, 544 and 546, various subclasses depending on substituents. Further restriction and election of species will be required if this group is elected.

Group 14: Claims 1-22, 24-30, and 44 (part of each), drawn to the remaining compounds of formula I that are not in formulae I-1 to I-15, and pharmaceutical composition thereof, classified in classes 514, 544 and 546, various subclasses

depending on substituents. Further restriction and election of species will be required if this group is elected.

Group 15: Claim 31, drawn to various processes of making compounds of formula I, classified in classes 544, 546, 548, etc., various subclasses depending on substituents. Further restriction and election of species will be required if this group is elected.

Group 16: Claims 33-43, drawn to various methods of use or treatment, classified in classes 514, various subclasses depending on substituents. Further restriction and election of species will be required if this group is elected.

Inventions of Groups 1 to 14 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are defined by distinct formulae I-1 to I-15, which would require a separate search and consideration. However, should applicant traverse on the ground that the 14 groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the 14 groups to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the invention unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The invention of group 15 is drawn to multiple processes of making compounds of formula I. It is obvious that formula I can be made by different processes. Therefore, a

reference that anticipated or rendered obvious the compounds, would not do so to the processes. Thus, a separate search would be required. Likewise, the invention of group 16 is drawn to various methods of use or treatment, which would also need additional searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and to search as well as examining the 16 distinct invention would indeed impose a serious burden on the examiner in charge of the instant invention, restriction for examination purposes as indicated is proper.

On 11-30-05, two attempts to contact Mr. David A. Dow at telephone no. 703-308-1202, and at telephone no. 203-792-6214 were unsuccessful. Thus, the restriction is presented in writing. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

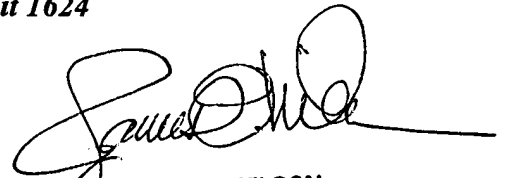


Tamthom N. Truong

Examiner

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11-30-05



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